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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,718	09/22/2003	R. Stephen Brown	14453	4655

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,718	BROWN ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 36-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *071704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

At Applicant's request, claims 36-41 are removed from Group III, and are now included in Group II because they depend from claim 18. It is believed that the previous examiner incorrectly incorporated claims 36-41 in Group III when they should have been incorporated in Group II.

Claims 1-23 and 36-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 May 2006.

Applicant's election with traverse of Group III, claims 24-41 in the reply filed on 11 May 2006 is acknowledged. The traversal is on the ground(s) that the apparatus of Group III can only be used according to the method of Group I, and therefore Groups I and III should be rejoined. This is not found persuasive because the product of Group III can be used in processes that are materially different from the process set forth in Group I. It is believed that the original examiner was correct in suggesting that the system of Group III "has separate utility as a standard fluorimeter, using higher concentrations of fluorescent materials which did not partition into the membrane." The limitation set forth in claim 24 that recites that the detector "detects fluorescence of said biological molecules partitioned into said partitioning element" merely represents an intended use. The apparatus of claim 24 is capable of fluorescing any sample or sample component, and is not limited to only the illumination of the partitioned material.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 24, 25 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Wolfbeis (US 5238809).

With respect to claims 24, Bentsen discloses a system for detecting the presence of microorganisms. The system includes a vessel in which the microorganisms in the sample are incubated. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An excitation light source is provided for irradiating the biological molecule, and a detector is used to detect any subsequent fluorescence from the biological molecule. The detected fluorescence is indicative of the presence of microorganisms in the sample. This is disclosed in column 2, line 54 to column 3, line 22 and column 16, line 11 to column 19, line 18. Column 24, lines 6-9 and 47-57 indicate that a controller is provided for regulating the operation of the light source. Bentsen, however, does not expressly disclose the use of a partitioning element that allows partitioning of the biological molecule thereinto.

Wolfbeis discloses a system in which the catalytic activity of enzymes is measured through the detection of emitted fluorescence. A vessel is provided in which microorganisms and enzymes are provided. Enzymes produced by the microorganisms are allowed to react with at least one substrate in order to produce a biological molecule. An optical fiber probe is inserted into the vessel for detecting the presence of the biological molecule. This is disclosed in column 9, line 63 to column 10, line 66. Column 6, lines 42-50 indicate that a partitioning element (Figure 4:23) is placed over

the optical fiber probe in order to separate desired biological molecules from other compounds in the sample solution.

Bentsen and Wolfbeis are analogous art because they are from the same field of endeavor regarding enzyme detection through fluorescence.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen with an optical fiber probe comprising a partition element in order to detect fluorescence from the produced biological molecule. In column 6, lines 42-50, Wolfbeis indicates that the use of partition elements is beneficial because they are permeable to the enzyme compound that is being detected, but impermeable to unwanted cellular components. This is desirable because it insures that all detected emission light is produced by enzyme-substrate biological molecules, and not by peripheral cellular molecules. In this way, more accurate measurements regarding the amount of biological molecules (and thereby the amount of microorganisms) in the sample solution can be obtained.

With respect to claims 25 and 28; Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Bentsen discloses in column 22, line 65 to column 23, line 5 and column 24, lines 7-9 and 47-57 that the apparatus is provided with control means for regulating the operation of the system, as well as control means for storing and outputting fluorescence data. A processor assembly (Figure 1:350) is provided for transmitting data electronically.

With respect to claims 29, 30 and 32, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. In addition, Bentsen discloses in column 17, lines 10-52 that the organism is *Escherichia coli*, and that the sample is selected from water, biological samples, food, and soil.

With respect to claims 31 and 33, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. Bentsen additionally indicates in column 16, lines 22-59 that beta glucuronidases and beta galacotsidases are known in the art as enzymes that are used in the detection of microorganisms. Column 3, lines 14-16 and column 16, lines 22-59 indicate that glucuronides and galactopyranosides are known in the art as acceptable substrates.

With respect to claims 34 and 35, Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. As previously noted, Bentsen discloses in column 22, line 56 to column 23, line 5 that the system includes optical components (Figure 1:340) for monitoring fluorescence detection. Bentsen teaches that fluorogenic dyes are attached to the substrate, and incorporated into the biological molecule formed by the substrate-enzyme reaction. This is disclosed in column 10, lines 7-14. If Wolfbeis's partition element was implemented in Bentsen's microorganism detection system (as suggested in the 35 U.S.C. 103 rejection of claim 24 above), the fluorescent dye would travel through the partitioning element with the biological molecule to the detection area. As already noted, the fluorescence of the dye

is detected by the detector, and the control unit uses the detected fluorescence to monitor fluorescence detection of the system.

2) Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen (US 6566508) in view of Wolfbeis (US 5238809) as applied to claim 24, and further in view of Lee (US 20030222012).

Bentsen and Wolfbeis disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of a removable cartridge in the vessel that is capable of containing the sample and the substrate. Bentsen and Wolfbeis do not disclose a removable cartridge containing a partitioning element.

Lee discloses a removable cartridge that comprises a mesoscale filter that is capable of partitioning cellular components in a sample. Detectable compounds are moved through the filter in an effort to remove undesirable cellular elements. The detectable compounds are then moved to a detector in order to verify their presence in the sample. This is disclosed in paragraphs [0008], [0012], [0016]-[0018] and [0045]-[0048]. Paragraph [0069] specifically states that the device is configured as a cartridge for easy insertion and removal from a vessel, and paragraph [0071] indicates that the device is used to biological microorganisms.

Bentsen, Wolfbeis and Lee are analogous art because they are from the same field of endeavor regarding microorganism detection devices.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Bentsen and Wolfbeis with a removable cartridge for containing the sample

and partitioning produced biological molecules. In paragraph [0069], Lee indicates that removable cartridges are beneficial because they can easily be moved from one reaction vessel to the next. Removable cartridges are known in the art to be reusable and therefore cost effective. Lee indicates in paragraphs [0012] and [0016]-[0018] that removable cartridges that employ partitioning membranes are especially beneficial because they represent a means by which biological molecules can be separated from undesirable cellular compounds that would otherwise interfere with accurate detection procedures.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Nelis (US 5861270), Kasila (WO 9932655) and Collins (EP 0044140) references disclose the state of the art regarding enzymatic detection of microorganisms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER